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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,127	10/16/2001	Steven Curtis Zicker	IR 6493-02	3786
23909 7590 06/29/2007 COLGATE-PALMOLIVE COMPANY 909 RIVER ROAD PISCATAWAY, NJ 08855				
			EXAMINER VAKILI, ZOHREH	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 06/29/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/978,127

Applicant(s)

ZICKER ET AL.

Examiner

Zohreh Vakili

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39, 44-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 39, 44-47 are presented for examination.

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed May 16, 2007 has been received and entered into the present application. Claims 39, 44-47 are pending and are herein examined on the merits.

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39, 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harper WO 00/44375 ('375) in view of Hamilton 6,335,361 (both references already of record).

Harper teaches a method for overcoming the problem of oxidative stress in a companion animal such as a dog or cat by increasing the plasma Vitamin E levels in the cat or dog. Specifically, a diet containing Vitamin C and Vitamin E are fed to senior (6.5-12.5 years of age) dogs. Harper discloses that such a vitamin "cocktail" will prevent or treat a disorder (aging), which has a component of oxidative stress. Additionally, Harper teaches a method of feeding vitamin E separately to the companion animal in order to increase the Vitamin E levels in the plasma thereby overcoming the problem of oxidative stress. Please see the abstract, page 1, lines 18-21; page 13, line 12; page 16, lines 20-23; Example 19, pages 47-48.

Harper does not teach adding antioxidants such as alpha lipoic acid or L-carnitine or mixtures thereof. Yet, the Examiner refers to Hamilton, which discloses a method of treating cognition disorders associated with aging. Specifically, the method involves administering an effective amount of a combination of the antioxidants carnitine and α -lipoic acid. A preferred form of carnitine is acetyl-L- carnitine and R- α -lipoic acid. Moreover, Hamilton teaches that the combination of antioxidants may be added to pet food for administration to animals such as cats, dogs, horses, birds and fish. The combination of antioxidants serves to inhibit age-related memory loss and provide

improved memory in older subjects. The combination of antioxidants contributes to the improvement of mental acuity. Finally, Hamilton discloses that additional nutrients such as vitamin E or C should be included as they are particularly important in older subjects. Please see col. 6, lines 44-60; col. 7, lines 14- 17; col. 8, lines 8-13; col. 10, lines 9-21.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of Harper to specifically administer to the aged dog or cat Vitamin E, C in combination with l-carnitine and α -lipoic acid because one of ordinary skill in the art would reasonably expect the combination of these anti-oxidant compounds to inhibit oxidative stress associated with aging. Moreover, since Hamilton discloses a method of improving memory in older pets as well as a method of treating cognitive disorders (e.g. age-related memory loss) by administering carnitine and α -lipoic acid, one of ordinary skill in the art would reasonably expect the combination of anti-oxidants not only to inhibit oxidative stress associated with aging but also to counteract age-related memory loss and improve mental acuity in the aged cats and dogs taught of Harper. Finally, even Hamilton suggests that additional administration of vitamin E or C would serve to enhance the treatment process by teaching that these anti-oxidants are particularly important in older subjects and should be included in the diet.

Concerning the claimed dosage amounts, since Hamilton and Harper establish that effective amounts, i.e. dosage amounts, are necessary to the treatment of disorders/symptoms associated with aging and oxidative stress, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further

modify the effective amounts of Hamilton and Harper such that the dosage amounts of the carnitine, vitamin E, vitamin C and alpha-lipoic acid are effective to inhibit oxidative stress or symptoms associated with aging in animals, thereby improving mental acuity and inhibiting age-related memory loss.

Response to Arguments

Applicant argues that Harper discloses using vitamin E and vitamin C for treating oxidative stress in a cat/dog and to treat a disorder associated with oxidative stress. Applicant further argues that though they are both antioxidants, they each have more than one mechanism of action and Harper does not teach their use for affecting learning ability in aged pets.

Harper discloses using vitamin E and vitamin C to overcome the problem of oxidative stress in a cat and dog and to prevent or treat a disorder affected by oxidative stress. Disorders such as ageing and neurodegenerative disease are caused by oxidative stress (see page 13, lines 6-14) and are treatable using the disclosed composition of Harper. As Applicant has mentioned, vitamin C and vitamin E are antioxidants that have several mechanisms of action. Applicant argues that the present invention differs from Harper because Harper does not teach that vitamin C and vitamin E affect learning in aged pets. However, one of the actions of vitamin C and E is to prevent or treat ageing in pets as taught by Harper due to its antioxidative action. Harper teaches a treatment for ageing which is associated with oxidative stress and the loss of learning ability is a

cognitive deficit which occurs with ageing.

Applicant asserts that Hamilton teaches using carnitine and lipoic acid to discourage age-related memory loss and provide improved memory, and further asserts that Hamilton does not teach the claimed objective of inhibiting the loss of learning ability or increasing learning ability.

Hamilton discloses a method of treating cognition disorders associated with ageing and to improve memory in older pets. Specifically, the method involves administering an effective amount of a combination of the antioxidants carnitine and alpha lipoic acid. A preferred form of carnitine is acetyl-L-carnitine and R-alpha-lipoic acid. The combination of anti-oxidants may be added to pet food for administration to animals such as cats or dogs. Hamilton even discloses that the combination of anti-oxidants contributes to the improvement of mental acuity and inhibits age-related memory loss and provides improved memory in older subjects. Finally, Hamilton discloses that additional nutrients such as Vitamin E or C should be included as they are particularly important in older subjects (please see col.6, lines 44-60; col. 7, lines 14-17; col. 8, lines 8-13; col. 10, lines 9-21). While memory and learning are distinct mental functions, at the same time they are related and function hand in hand. With no memory there will be no retention of the learning. Therefore, whatever learned can be easily forgotten with lack of memory and, therefore, improved memory provides an increase in learning ability. Applicant's claimed method steps are obvious in view of the prior art. The Hamilton reference renders the claimed invention obvious and the rejection is respectfully maintained.

Applicant argues the actual physiological and biochemical mechanisms of action involved in the actual processes of learning and memory is different and further Applicant argues that the Examiner has not provided no scientific evidence that learning and memory are related. Examiner does not agree that the actual physiological and biochemical processes involved with learning and memory is different. Stedman's Medical Dictionary defines cognition as a generic term embracing the mental activities associated with thinking, learning, and memory. The Office of United States Patent doesn't have any testing facilities such as laboratories. The burden of providing scientific proof, test and results are on the Applicant not the Examiner.

Applicant has not provided any reasoning or evidence as to why the combined antioxidative effect for the treatment of aging in the aged pets would not have necessarily resulted from the combination of Harper and Hamilton. Administration of the same products, for example, vitamin E, vitamin C, lipoic acid and carnitine, to an identical host (i.e. an aged pet) would have the same effect on learning as that claimed because products of identical compounds cannot have mutually exclusive properties. Applicant argues that the Examiner has reached this conclusion only through the impermissible use of hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner
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June 11, 2007

 4/25/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER